

OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CM37002-05

Amendment No.: 1

Date of Issuance: 10/03/2012

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment revises the RFP as stated below:

Questions and answers:

1. How many different products (i.e. are some the same product in different strengths?)

There are drug products with different strengths which are on stability. The total number of lots on stability is given in the RFP under the technical proposal instructions and on the attached document "Technical Proposal Instructions"

2. Are these controlled or Potent compounds?

These are potent anti-cancer agents.

3. How many require dissolution testing?

- a. What type of product? (extended release vs. immediate release)?

There are no extended release products on stability currently.

- b. Specifications would be very helpful.

The release specifications will be provided at the time of the award.

4. The Conditions for storage?

The stability storage conditions are given in the RFP under the technical proposal instructions and on the attached document "Technical Proposal Instructions"

5. The package type/size/number and orientation of parenteral and Oral dosage forms?

- a. This is important for determining storage needs.

The total storage requirement under various stability conditions is specified in the RFP under the technical proposal instructions and on the attached document "Technical Proposal Instructions"

6. Will these studies start all together or will these be staggered over time?

The stability start date is different for different lots and staggered over time.

7. Please define what "Dedicated" means as it relates to Statement of Work 08/08/12, Section B, Paragraph 4.

The RFP calls for HPLC instruments which are readily available to carry out the analyses as stability samples are pulled.

8. Is the drug product owned by NCI?

All stability batches are produced by NCI contractors and for agents being studied by NCI.

9. Regarding past performance information, is the Government requesting only information concerning contracts completed within the past "One year"? Or should the past performance information include a period longer than the past One year? Also, can you clarify the term "completed". For example, does "completed" mean only contracts that have ended and been completed by the Contractor within the past One year (with no possible additional periods of performance), or does "completed" include contracts where an incremental contract year was completed, but which may have additional incremental contract years to be performed depending on the Government's contract authorization?

Completed within the last year means the contract is finished with no work being performed. But any ongoing contract that is for similar work is acceptable to include even if it was awarded more than one year ago.